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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/836,455	05/09/97	CHATTERJEE	M 304142000322

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EXAMINER

TRAN, M

ART UNIT

PAPER NUMBER

1642

24

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/836,455

Applicant(s)

CHATTERJEE ET AL.

Examiner

MAU T TRAN

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-12, 14-19, 38, 41, 44, 45 and 57-73 is/are pending in the application.
- 4a) Of the above claim(s) 67-69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12, 14-19, 38, 41, 44-45, 57-58, 59-66 and 70-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 20.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

1. This application is a 371 of PCT/US96/20757 filed on December 19, 1996 and claims priority to US Application 08/766350 filed on December 13, 1996 and claims the benefit of provisional application 60/035345 filed January 29, 1996 converted from US Application 08/591965 on August 1, 1996. An amendment was received on October 3, 2000 and entered in which claims 13 was cancelled, claims 6-12, 14-15, 19, 38, 41, 44-45 were amended and new claims 62-73 were entered. It was noted by the office that Applicant had inadvertantly placed the wrong serial number in the REMARK section of the amendment, thus the amendment was entered into the application later than usual. The amendment filed on December 4, 1999, pg. 5 remarked that Applicant request the rejoinder of presently excluded method claims to the extent that they incorporate all the limitations of the product claims. This request is denied as no references to which claim numbers Applicant is requesting.

Claims 6-12, 14-19, 38, 41, 44-45, 57-58 and new claims 59-66 and 70-73 are pending in the instant application.

Election/Restrictions

2. Newly submitted claims 67-69 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are drawn to a method of making the polypeptide of 11D10 by recombinant technique which is different from the product claims that are pending in the instant application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 67-69 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Claims 6-12, 14-19, 38, 41, 44-45, 57-58, 59-66 and 70-73 are examine on the merits.

Priority

3. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a 371 of Application No. PCT

US96/20757, filed December 19, 1996." should be entered following the title of the invention or as the first sentence of the specification. Also, the current status of all nonprovisional parent applications referenced should be included.

It is also noted by the Examiner that the reference, in the amendment to the instant application filed October 3, 2000, to Provisional Application No. 60/035,345 filing date of January 29, 1996 does not correspond with the filing date of the oath/declaration for this reference application which is January 26, 1996. Proper correction is required.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The filing date of Application 60/035345, to which the instant application claims priority is incorrect and does not match with the referenced date in the specification. The filing date for Application 60/035345 is January 29, 1996. Proper correction is required.

THE REJECTIONS

1. REJECTIONS MAINTAINED

a. Claims 14, 15, 57, 58 and 72-73 were rejected under 35 USC 112, first paragraph, SCOPE rejection. Upon review of applicant's argument and amendment to the claims, the rejection is maintained.

Claims 14, 15, 57, 58 and 72-73 are drawn to a polynucleotide comprising of at least 15 nucleotides encoding CDRs of either light chain or heavy chain of SEQ ID NO: 2 and 4. The scope of the claim is not commensurate with what is disclosed in the specification. The claims read on all polynucleotide sequences which have at least 15 nucleotide in SEQ ID: 2 and 4 but does not specifically state which area of the sequence contain the essential 15-mer. The claims read on any span of nucleotide sequence as well as on the entire antibody itself because of the "comprising" language.

Applicant has only taught the specific nucleotide sequence consisting of SEQ ID NO:2 and 4 of 11D10 antibody of ATCC No. HB-12020.

b. Claims 15 and 58 were rejected under 35 USC 102(b) as anticipated by Mo et al, Liu et al, DeWaele et al. Upon review of Applicant's amendment to the claims, the rejection is maintained. Claim 15 still reads on a nucleotide of at least 15 nucleotide sequence of SEQ ID NO:3 which is anticipated by either Mo et al, Liu et al or DeWaele et al as evidenced by the computer sequence alignment.

c. Claims 15 and 58 were rejected under 35 USC 102(e) as being anticipated by Gourlie et al (US 5808033). Upon review of Applicant's amendment to the claims, the rejection is maintained for the reasons as set above under the 102(b) rejection.

d. Claims 14 and 57 were rejected under 35 USC 102(b) as being anticipated by Shlomchik et al, Kavalier et al, Seidman et al, or Darsley et al. Upon review of Applicant's amendment to the claim, the rejection is maintained. Claim 14 still reads on a nucleotide of at least 15 nucleotide sequence of SEQ ID NO:1 which is anticipated by either Shlomchik et al, Kavalier et al, Seidman et al, or Darsley et al as evidenced by the computer sequence alignment.

e. Claims 15 and 58 were rejected under 35 USC 102(e) as being anticipated by Bendig et al (US 5840299). Upon review of Applicant's amendment to the claims, the rejection is maintained for the reasons as set above under the 102(b) rejection.

f. Claims 6-12, 16-19, 38, 41, 44, 45, 59-66 and 70-72 were rejected under 35 USC 102(b) as being anticipated by Chatterjee et al (Antigen and Antibody Mol. Engineering, 1994, Cancer Immunol. Immunother., 1994) and Chakraborty et al (Proc. Am Assoc Cancer Res., 1994) and upon review of Applicant's argument and the submission of Declarations under 1.132 by S. Chatterjee, M. Chatterjee and K. Foon, the rejection is maintained.

Claims 6-12, 16-19, 38, 41, 44, 45, 59-66 and 70-72 are drawn to a polynucleotide comprising a sequence encoding the antibody of 11D10 which contains 3 light chains and 3 heavy chains of the CDR region of 11D10 without mention of the specific sequences of the CDRs. Because of the broadness of the claims as amended, the claims read on all antibodies which contain CDR regions of 11D10 which also

includes naturally occurring antibody encoded by the natural genetic sequences or antibodies encoded by the hybridoma that was used in the references cited above. However, Applicants have declared that to Applicant's best knowledge, the antibody was not made publicly available before the filing date of the instant application. However, evidence to the contrary was noted by the Examiner because Applicant's publication in Cancer Research (Vol. 55, pp. 1525-30, April 1995) required that the authors agree to make freely available to others any biological materials which was not commercially available that were used in the research reported, in the instant case, 11D10 hybridoma (see Cancer Research, January 1, 1995, Vol. 55(1):pp.202-208, especially pg. 207, under "Policy..". Therefore, the declaration does not overcome the rejection and the rejection is maintained.

2. All other rejections as previously cited in the Office Action in Paper #15 is withdrawn upon review of Applicant's amendment to the claims and arguments.

3. NEW REJECTIONS

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 14, 15, 57, 58 and 72-73 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 14, 15, 57, 58 and 72-73 are drawn to a polynucleotide sequence encoding an immunoglobulin variable regions containing CDRs of SEQ ID NO: 2 or 4 or comprising a 15mer of SEQ ID NO: 1 or 3. The claims read on nonpatentable statutory subject matter. Inclusion of the word "isolated" in the claims will obviate this rejection.

4. **REJECTION UNDER 35 USC 112, 1ST ENABLEMENT**

The specification is objected to and claims 6-12, 16-19, 38, 41, 44, 45, 59-66 and 70-72 are rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an

adequate written description of the invention and failing to provide an enabling disclosure, because the specification does not provide evidence that the claimed biological materials are (1) known and readily available to the public; (2) reproducible from a written description (e.g. sequenced); or (3) deposited.

It unclear if a cell line which produces an antibody having the exact structural and chemical identity of 11D10 is known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

The instant application does not provide the appropriate evidence of satisfying the deposit of the cell line producing 11D10 antibody for the enforceable life of the patent.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications. Applicant's provision of these assurances would obviate this objection/rejection.

Affidavits and declarations, such as those under 37 C.F.R. § 1.131 and 37 C.F.R. § 1.132, filed during prosecution of the parent application do not automatically become a part of this application. Where it is desired to rely on an earlier filed affidavit, the applicant should make the remarks of record in the later application and include a copy of the original affidavit filed in the parent application.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mau Tran whose telephone number is 703-605-1165. The examiner can normally be reached on Monday-Friday from 8:00 a.m. – 5:30 p.m. with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. Any inquiry of a general


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nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Mau Tran, Ph.D.

Patent Examiner, Art Unit 1642

April 10, 2001


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
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